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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,305

02/24/2004

R. Elaine Fulton

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09/15/2006

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WASHINGTON, DC 20036

EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/784,305

Applicant(s)

FULTON ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

—The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

THE REPLY FILED 30 August 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See attached. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 4 and 7-9.
Claim(s) objected to: _____.
Claim(s) rejected: 10.
Claim(s) withdrawn from consideration: 1-3 and 11-15.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Advisory Action

The objection to claims 4 and 7-10 is withdrawn in view of Applicant's amendment filed August 30, 2006.

Specification

The specification, as amended in the amendment filed January 23, 2006, remains objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. Applicant's arguments have been carefully considered and are addressed below.

- With regard to 37 CFR 1.57 (b)(1) and (2), Applicant asserts that there is a clear intent to incorporate the Alvi *et al.* reference. Applicant's specification recites, "In addition, the List of Prior Art Literatures referred to in the Background of the Invention section is incorporated by reference herein." Applicant argues that there is no need to incorporate a "list" only, as opposed to the references themselves. The intent of the statement, "the List of Prior Art Literatures referred to in the Background of the Invention section is incorporated by reference herein", was to incorporate the references themselves.
 - In response to Applicant's argument, the Office agrees that Applicant's statement expresses a clear intent to incorporate the references listed in the Background section of the specification, including the Alvi *et al.* reference.
- With regard to 37 CFR 1.57 (c), Applicant argues that the specification clearly presents the citation and teachings of Alvi *et al.* in the Background of the Invention section.

Applicant points to page 6 of the specification which states,

"[T]he present inventors have previously cloned and characterized several single-chain variable fragment antibodies (scFv Abs) against VEE (Alvi *et al.* 1999; Alvi

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et al., 2002; Alvi *et al.*, 2003). Among them, mA116 scFv Ab was well characterized, showing sensitivity and specificity in recognition of VEE by immunoassay (Alvi *et al.*, 2003)."

Applicant argues that such statements in the Background of the Invention section clearly demonstrate that the mA116 scFv Abs are deemed by the inventor to be non-essential material.

- In response to Applicant's assertions, it appears that Applicant is relying on two things: 1) the mA116 scFv Abs were referenced in the Background of the Invention section, implying that information presented in the Background of the Invention section is not essential material; and 2) the mA116 scFv Ab was well characterized, also implying that information relating to mA116 scFv Ab is not essential material because it was already known at the time of the invention.
- The Office has considered Applicant's assertions, however, the claims require a mA116 scFv Ab. Previously, the Office considered "a mA116 scFv Ab" to be a single entity, not a reference to a *species* of mA116 scFv. Since a mA116 scFv Ab is required to practice the invention in claim 10, it is deemed to be essential material. Whether it was already known (referenced in the Background of the Invention section, disclosed in U.S. Patent 6,818,748, and "well characterized") does not alter its being essential to practice the invention. Since the Office deems the material to be essential, its incorporation by reference from a non-patent literature source is not acceptable.
- Applicant notes that original claim 4 was directed to a fusion protein, SBP tagged scFv Ab, comprising a single-chain variable fragment antibody (scFv Ab) fused with a

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streptavidin-biotin peptide (SBP) sequence. Applicant asserts that the scFv Ab was not limited to the mA116 scFv Ab, even though it was a preferred embodiment of the present invention.

- The Office requests further clarification on the meaning and implications of Applicant's comment above.

In view of 37 CFR 1.57 (c), the Office maintains its position that Applicant is attempting incorporate essential material by reference from a source other than a U.S. patent or U.S. patent application publication. The incorporation by reference of Alvi *et al.* is improper because Alvi *et al.* is not a U.S. patent or U.S. patent application publication. The antibody scFvs listed above are essential material because they are required to provide a written description of the claimed invention.

Claim Rejections - 35 USC § 112

Claim 10 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following. (The Office notes that Applicant has pointed out support in Alvi *et al.* for all of the scFvs, including mA116-6.)

- Applicant notes that to satisfy the written description requirement under U.S. practice, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Applicant asserts that the subject matter of claim 10 is described in the

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specification and claims in sufficient detail via words and structures to establish that the inventor had possession of the claimed invention. In particular, Applicant notes that scFv Ab is defined as a mA116 scFv Ab which according to the description in the Background of the Invention section of the specification is a well-characterized scFv Ab against VEE based on previously known publications.

- Applicant argues that given the examples of mA116 scFv Abs and their respective Deposit Accession Numbers provided by the Applicants, and the teachings of the structures of the claimed fusion protein in the incorporated references, specification and claims, Applicant has clearly established possession of the claimed invention.
 - In response to the arguments presented above, had the subject matter of claim 10 been properly incorporated by reference, the disclosure would have been sufficient to meet the written description requirement. However, for the reasons discussed above relating to the incorporation by reference of mA116 scFv Ab species, written description is not adequately met by the disclosure.
- Applicant notes that the amendment to claim 10 was presented in the previously filed response to put the claim in better form under U.S. practice by introducing the proper article, “a” before the newly introduced element of “mA116 scFv Ab”.
 - In response, the Office acknowledges the reason for the amendment. The amendment also revealed that there is more than one mA116 scFv Ab, and that any of the mA116 scFv Abs are intended to be encompassed and claimed.

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Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 9/14/06
STACY B. CHEN
PRIMARY EXAMINER